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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,106	01/30/2001	Frederick M. Ausubel	00786/362002	2344

7590
Karen L Elbing
Clark & Elbing
176 Federal Street
Boston, MA 02110

12/19/2001

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1656

8

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/581,106

Applicant(s)
Ausubel et al.

Examiner
Joyce Tung

Art Unit
1656



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 3-6 and 11 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Art Unit: 1656

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1656.

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

- /2. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form since the language "facilitated" is unclear what is meant regarding to the detection step via said hybridization tag.

Claim Rejections - 35 USC § 112

3. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 1-20 are vague and indefinite because of the language "opposite strands" in claims 1 and 14. It is unclear what is the definition of the language. Further, it is unclear what is

Art Unit: 1656

the definition of the language "bordering the position of said polymorphic sequence" in claims 1 and 14. It is suggested to clarify uncertainty.

b. Claims 1-20 are vague and indefinite because of the language "being non-complementary to said nucleic acid sequence at a single non-complementary nucleotide in its 3'-terminal nucleotides 2-6". It is unclear what is meant by the language.

not clear
c. Claims 2-5 are vague and indefinite because it is unclear what is meant by the language "different ranges of specificity" in claim 2. Further, it is unclear what is meant by the language "3000-fold range of specificity". Does it mean that the specificity is within the range of 3000 nucleotides sequence long. It is suggested to clarify uncertainty.

d. Claims 8-9 are vague and indefinite because it is unclear what is meant by the language "a universal primer binding site". Particularly, the language "universal primer" is unclear what is meant. Does it mean that the primer is not specific? It is suggested to clarify uncertainty.

e. Claims 10-13 are vague and indefinite because it is unclear what is meant by the language "a unique hybridization tag". Does it mean that the hybridization tag has a label on it? It is suggested to clarify uncertainty.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1656

5. Claims 1-2, 7, 9 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sorenson et al. (5,496,699).

Sorenson et al. disclose a method of detecting mutated genes and oncogenes via amplification (See the abstract) in an allele specific manner to distinguish a normal gene sequence from a mutated gene sequence present in the sample (See column 2, lines 19-23). The method applies four primer pairs including a set of four allele-specific first primers complementary to the gene sequence contiguous with the site of the mutation on the first strand and at 3' nucleotide it is complementary to one of three possible mutations which can occur at this known position (See column 2, lines 27-33). These primers are unique with respect to each other and differ only at the 3' nucleotide (See column 2, lines 29-33) (as recited in the limitations of claims 1-2 and 14). the amplified product can be separated from the reaction mixture by adsorption to avidin or streptavidin attached to a solid support (See column 10, lines 33-44) (as recited in the limitations of claim 12). The method of this invention may embodied in diagnostic kits including reagents for the isolation of DNA as well as sets of primers used in the detection and reagents used in the amplification (See column 9, lines 29-41) (as recited in the limitations of claims 15-20). The disclosure of Sorenson et al. also involves labeled primers for the detection of the amplified product (See column 8, lines 21-25) (as recited in the limitations of claim 9).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1656

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorenson et al. (5,496,699) as applied to claims 1-2, 7, 9 and 14-20 above, and further in view of Mullis et al. (4,965,188).

The teachings of Sorenson et al. are set forth in section 5 above and Sorenson et al. do not disclose using a hybridization tag, but Sorenson et al. indicate that the amplified products are attached to a solid support by adsorption to avidin or streptavidin (See column 10, lines 33-38). This is inherent that there is a binding partner for the immobilization (as recited in the limitations of claim 12)

Mullis et al. disclose detecting the amplified product by using sequence specific oligonucleotide affixed to a membrane (See column 5, lines 3-12). Mullis et al. also disclose

Art Unit: 1656

using a labeled oligonucleotide probe for mutation detection (See column 4, lines 43-46 and lines 60-65).

One of ordinary skill in the art at the time of the instant invention would have been motivated to modify the method of Sorenson et al. by using a sequence-specific labeled oligonucleotide for the detection because by using the sequence-specific labeled oligonucleotide probe, it increases the specificity for mutation detection as disclosed by Mullis et al. that the process is especially useful in detecting nucleotide variations with only very small amounts (See column 38, lines 25-30). It would have been prima facies obvious to carry out the method as claimed.

Allowable Subject Matter

8. Claims 3-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Art Unit: 1656

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

December 14, 2001

A handwritten signature in black ink, appearing to read "E Campbell". The signature is stylized with a large, looped "E" and a cursive "Campbell".

EGGERTON A. CAMPBELL
PRIMARY EXAMINER